

The opinion in support of the decision being entered today is not binding precedent of the Board.

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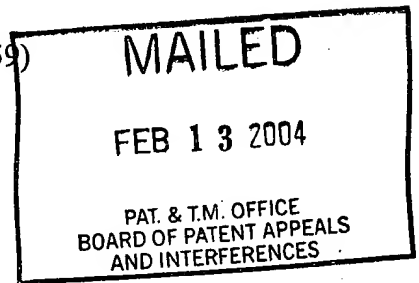
BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

ALBERTO STAMPA, PELAYO CAMPS, GLORIA RODRIGUEZ,
JORDI BOSCH and MARIA DEL CARMEN ONRUBIA

Junior Party,
(U.S. Patent No. 6,084,100
and U.S. Reissue Application No. 10/234,659)

v.

WILLIAM P. JACKSON
Senior Party,
(U.S. Patent No. 6,093,827 and
U.S. Application No. 09/525,894)



Patent Interference No. 105,069 (MPT)

Before: SPIEGEL, LANE and TIERNEY, Administrative Patent Judges.

TIERNEY, Administrative Patent Judge.

DECISION ON PRELIMINARY MOTIONS

This case is before a preliminary motions panel. No oral hearing was held prior to rendering this decision as the parties did not request such a hearing.

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I. Summary of Decision

This interference is directed to processes for making loratadine. Loratadine is said to be the active pharmaceutical ingredient in the antihistimine sold by Schering Corporation under the brand name Claritin®.

Generally, both parties claim processes for the manufacture of loratadine by coupling carbonyl compounds with low-valent titanium via a McMurry reaction. The two parties' claims differ in that Stampa's claims explicitly require the presence of a tertiary amine whereas Jackson's claims do not.

A key question posed by the parties is whether Stampa's "amine" loratadine process claims are patentably distinct from Jackson's loratadine process claims. Specifically, Jackson argues that there is no interference in fact by contesting the APJ's construction of Jackson's "consisting essentially of" claims and the obviousness of Stampa's amine process. Based upon the record presented, the panel concludes that there is an interference in fact between the parties as: 1) Jackson's claims are open to the inclusion of an amine and are anticipated by Stampa's claims; and, 2) Stampa's claims are rendered obvious by Jackson's claims taken in light of the well known use of tertiary amines for McMurry reactions.

Stampa contests the patentability of Jackson's claims due to alleged lack of definiteness, enablement and written description stemming from their breadth. Stampa also alleges that Jackson is not entitled to the accorded priority benefit dates of Jackson's earlier filed PCT and Great Britain ("GB") applications. We have considered the record and determined that Stampa has failed to sufficiently demonstrate that certain Jackson's claims directed to a process of

manufacturing loratadine are unpatentable under 35 U.S.C. §112, first and second paragraphs.

The panel has also determined that Jackson is entitled to benefit, for the purposes of priority, of its earlier PCT and GB applications as they describe and enable a process within the scope of Count 1.

Additionally, Stampa seeks to strike or suppress certain Jackson evidence for failing to comply with the Federal Rules of Evidence, the USPTO interference rules and the Standing Order (Paper No. 2). As Stampa failed to timely object to the disputed evidence, Stampa's motion to strike or suppress is denied.

II. Procedural History

The two parties in this interference, Jackson and Stampa, are currently involved in a 35 U.S.C. §291 interference between the involved Jackson(U.S. Patent No. 6,093,827) and a Stampa (U.S. Patent No. 6,084,100) patents in the United States District Court for the Southern District of New York. The District Court determined that there was no interference-in-fact between the parties' patents. *MediChem, S.A. v. Rolabo, S.L.*, Civ. Action No. 01-CV-3087 (S.D.NY., filed May 7, 2002). The Federal Circuit recently reversed the District Court's decision and remanded for further proceedings. *Medichem v. Rolabo*, slip opinion 02-1461, -1480 (Fed. Cir., Dec. 23, 2003).

Both Stampa and Jackson have pending applications before the United States Patent & Trademark Office that claim benefit of the patents involved in the §291 proceeding.¹ Based upon the record at the outset of the interference, the Administrative Patent Judge ("APJ") designated to handle this interference determined that the parties' respective applications *prima facie* interfered with their opponent's related patent. Specifically, Jackson's patent and application claims were construed as open to the inclusion of the amine and thus, anticipated by Stampa's claims. Further, Stampa had admitted that the claims of their patent and reissue application were obvious over Jackson in light of the well known use of amines in a McMurry reaction. Based upon the apparent anticipation of Jackson's claims and the admitted obviousness of Stampa's claims, the APJ declared the interference.

III. Finding of Facts

1. Real Parties in Interest

A. Junior Party

1. Medichem, U.S.A. is said to be the real party in interest for Stampa's Reissue Application No. 10/234,659 ("659 application") and U.S. Patent No. 6,084,100 ("100 patent"). (Stampa Designation of Real Party in Interest, Paper No. 4).

¹Jackson Application Serial No. 09/525,894 claims benefit of Jackson, U.S. Patent No. 6,093,827. Stampa Application Serial No. 10/234,659 is a reissue of Stampa, U.S. Patent No. 6,084,100. (Notice Declaring Interference, Paper No. 1, pages 5-6).

B. Senior Party

2. Rolabo S.L. is said to be real party in interest for Jackson's U.S. Application No. 09/525,894 ("894 application") and U.S. Patent No. 6,093,827 ("827 patent"). (Jackson Real Party in Interest, Paper No. 8).

2. Accorded Priority Benefit

A. Junior Party

3. Stampa's U.S. Reissue '659 application was filed September 3, 2002. Solely for the purpose of priority, Stampa's '659 Reissue application has been accorded the filing date benefit of:

- i. U.S. Patent No. 6,084,100, issued on July 4, 2000, based upon U.S. Application No. 09/058,837, filed April 13, 1998; and,
- ii. U.S. Provisional Application No. 60/048,083, filed May 30, 1997.

(Notice Declaring Interference, Paper No. 1, p. 17).

4. Stampa's U.S. Patent No. 6,084,100, issued on July 4, 2000, based upon U.S. Application No 09/058,837, filed April 13, 1998. Stampa '100 has been accorded the benefit of U.S. Provisional Application 60/048,083, filed May 30, 1997. (Notice Declaring Interference, Paper No. 1, p. 18).

B. Senior Party

5. Jackson's U.S. Application 09/525,894 ("894"), was filed March 15, 2000, as a continuation of U.S. Application Serial No. 09/383,078. Solely for the purpose of priority, Jackson's '894 application has been accorded the filing date benefit of:

- i. U.S. Patent No. 6,093,827, issued July 25, 2000, based on U.S. Application No. 09/383,078, filed August 26, 1999; and,
- ii. PCT Application PCT/GB98/00605, filed February 26, 1997; and UK Application 9703992, filed February 26, 1997.

(Notice Declaring Interference, Paper No. 1, p. 20).

6. Jackson's U.S. Patent No. 6,093,827 issued July 25, 2000, based on U.S. Application No. 09/383,078, filed August 26, 1999. It has been accorded the benefit of filing dates of:

- i. PCT Application PCT/GB98/00605, filed February 26, 1997; and
- ii. UK Application 9703992, filed February 26, 1997.

(Notice Declaring Interference, Paper No. 1, p. 19).

3. The Count and Claim Correspondence

7. Count 1, the sole count in the interference, is claim 17 of Jackson's U.S. Patent No. 6,093,827. The claims of the parties are as follows:

Jackson, U.S. Patent No. 6,093,827:	1-17
Jackson, U.S. Application No. 09/525,894:	1-28
Stampa, U.S. Patent No. 6,084,100:	1-13

Stampa, U.S. Application No. 10/234,659: 1-18

The claims of the parties which correspond to Count 1 are:

Jackson, U.S. Patent No. 6,093,827:	1-17
Jackson, U.S. Application No. 09/525,894:	1-28
Stampa, U.S. Patent No. 6,084,100:	1-13
Stampa, U.S. Application No. 10/234,659:	1-18

The claims of the parties which do not correspond to Count 1 are:

Jackson, U.S. Patent No. 6,093,827:	None
Jackson, U.S. Application No. 09/525,894:	None
Stampa, U.S. Patent No. 6,084,100:	None
Stampa, U.S. Application No. 10/234,659:	None

(Notice Declaring Interference, Paper No. 1, p. 21).

4. Person of Ordinary Skill in the Art

8. A person of ordinary skill in this field would be a synthetic chemist with at least a Bachelor degree in chemistry or a closely related discipline and who possesses an ability to appreciate the coupling of carbonyl compounds with low-valent titanium, i.e., a McMurry reaction. (See, JX 1003, ¶¶ 1-2, SX 2011, ¶¶ 1-3, JX 1001, Dr. Lectka trial testimony, A004711, line 9 to A004713, line 15).

5. Jackson's U.S. Patent No. 6,093,827

A. Jackson's Independent Claim 1 and Dependent Claim 17

9. Jackson's claim 17 is also Count 1 and reads as follows:

17. A process as claimed in claim 1 for preparing Loratadine.

(JX 1001, A000109; Jackson '827 patent, claim 17).

10. Jackson's claim 1 reads as follows:

1. A process for preparing 5,6-dihydro-11H-dibenzo[a,d] cyclohept-11-enes comprising reacting a dibenzosuberone or an aza derivative thereof with an aliphatic ketone in the presence of low valent titanium wherein said low valent titanium is generated by zinc.

(JX 1001, A000108; Jackson '827 patent, claim 1).

B. Jackson's Specification

11. Jackson's '827 patent specification is directed to a process for the preparation of 5,6-dihydro-11H-dibenzo[a,d] cyclohept-11-enes, such as loratadine. (JX 1001, A000106; Jackson '827, col. 1, lines 6-8).

12. Jackson's process may be conducted by reacting a dibenzosuberone or an aza derivative with an aliphatic ketone in the presence of low valent titanium. (JX 1001, A000106; Jackson '827, col. 2, lines 18-20).

13. Jackson's specification discloses that the invention "seeks" to use less hazardous materials, improve yields and selectivity as compared to prior processes. (JX 1001, A000106; Jackson '827, col. 2, lines 11-17).

14. Jackson discloses that an aspect of their invention involves conducting the process in the presence of the low valent titanium generated by zinc. (JX 1001, A000106; Jackson '827, col. 2, lines 18-24).

15. The process of Jackson is conducted such that the "reaction proceeds through an intermediate diol." (JX 1001, A000107; Jackson '827, col. 3, lines 9-11).

16. The reaction may be conducted in ethereal solvents that are commonly used in coupling reactions involving titanium. Examples of ethereal solvents include tetrahydrofuran, dioxane, and dimethoxyethane. (JX 1001, A000107; Jackson '827, col. 4, lines 4-7).

17. Jackson '827 provides three examples of the allegedly patentable process. Example 3 describes the preparation of loratadine and reads as follows:

8-Chloro-5,6-dihydro-11H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-one (2.45 g, 10 mmole) (see J. Heterocyclic Compounds, vol. 8, 1971, page 73) and 4-carboethoxypiperidone (1.8 g, 10 mmole) are dissolved in 30 ml tetrahydrofuran. Zinc (5 g, 78 mmole) is added and the mixture cooled to 0.degree. C. Titanium tetrachloride (3 ml, 27 mmole) is added over about 10 minutes. The mixture is then heated at reflux for 1 hour. The mixture is added to 100 ml water and 50 ml toluene. Most of the aqueous phase is separated and the organic phase is washed with 20 ml ammonium hydroxide solution. The mixture is filtered through celite and the celite washed with a further 50 ml toluene. The organic phase is separated and dried over magnesium sulphate. The solvent is removed and the residue (3.75 g) is crystallised from butyl ether to give 2.5 g loratadine (68%). HPLC shows the product to be >98% pure.

(JX 1001, A000108; Jackson '827, Example 3, col. 5, lines 11-33, paragraphing omitted).

18. One skilled in the art would understand Jackson '827 Example 3 as describing:
- a) a process conducted in the presence of a "disuborone or aza derivative" (8-Chloro-5,6-dihydro-11H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-one);
 - b) that is reacted with an aliphatic ketone (4-carboethoxypiperidone)
 - c) in the presence of titanium (titanium tetrachloride) and zinc.
- (JX 1001, A000108; Jackson '827, Example 3, col. 5, lines 11-33).

6. Jackson's U.S. Application No. 09/525,894

19. Claim 1 of Jackson's '894 application is identical to Jackson's '827 patent except that the '894 application employs a "consisting essentially of" transition as opposed to the "comprising" transition used in the '827 patent. (Jackson Clean Copy of Claims, Paper No. 7).

20. Claim 17 of Jackson '894 reads as follows:

A process as claimed in any preceding claim for preparing Loratadine.

7. Stampa's U.S. Patent No. 6,084,100

A. Stampa's Claim

21. Stampa's claim 1 reads as follows:

1. A process for the preparation of loratadine consisting of reacting, in an organic solvent and in the presence of tertiary amine, 8-chloro-5,6-dihydrobenzo[5,6]cyclohepta[1,2-b]pyridine-11-one, of formula VII and ethyl 4-oxopiperidine-1-carboxylate of formula IV with low-valent titanium species.

(JX 1001, A00104; Stampa '100, col. 5, line 58 to col. 6, line 17).

22. Stampa's claim 2 reads as follows:

2. The process of claim 1, wherein the low-valent titanium species are generated by reduction of titanium tetrachloride with zinc dust.

(JX 1001, A00104; Stampa '100, col. 6, lines 22-24).

B. Stampa's '100 Specification

23. Stampa's '100 patent is directed to a process for the preparation of loratadine. (JX 1001, A000103; Stampa '100, col. 3, lines 4-27.)

24. Stampa's process is characterized by reacting, in an organic solvent and in the presence of tertiary amine, 8-chloro-5, 6-dihydrobenzo [5,6] cyclohepta [1,2-b] pyridine-11-one and ethyl 4-oxopiperidine-1-carboxylate with a low-valent titanium species. (JX 1001, A000103; Stampa '100, col. 3, lines 4-27).

25. Stampa '100 discloses that the conversion of the starting compounds into loratadine occurs by the reductive cross coupling of the McMurry reaction. (JX 1001, A000103; Stampa '100, col. 3, lines 28-30).

26. Stampa '100 states that the use of titanium tetrachloride in combination with zinc dust is highly preferred because titanium chloride is very expensive and unstable versus the air oxygen and the humidity. (JX1001, A000103; Stampa '100, col. 3, lines 62 to 65).

27. Stampa's '100 specification teaches that any inert solvent can be used, but preferably the solvent is an ethereal solvent such as diethyl ether, 1,4-dioxane, 1,2-dimethoxyethane, or tetrahydrofuran. (JX1001, A000103; Stampa '100, col. 3, lines 66 to 67 and col. 4, lines 1 to 3).

28. Stampa provides an example of their alleged inventive process, in which a tertiary amine, zinc, and titanium chloride are used in the preparation of loratadine. (JX1001, A000103; Stampa '100, col. 4, line 49 to col. 5, line 57).

8. Expert Witnesses

A. Jackson's Expert Witness, Professor John E. McMurry, Ph.D.

29. John E. McMurry, Ph.D. is a full professor in the Department of Chemistry at Cornell University, where he has been teaching since 1980. He received his Ph.D. from Columbia University in 1967, and his B.A. from Harvard University in 1964. His research interests focus on organic synthesis, including the development of new synthetic methods and the synthesis of unusual molecules, both natural and unnatural. (Second Declaration of Professor John E. McMurry, Ph.D., SX 2011, ¶ 1).

30. Dr. McMurry's expertise in the field of low-valent titanium carbonyl coupling reactions dates back to 1973 when he discovered that ketones and aldehydes undergo reductive dimerization to yield olefins on treatment with low-valent titanium reagents. This coupling reaction has been named after him, and is known as the "McMurry Reaction." (SX 2011, ¶ 2).

31. Dr. McMurry testifies that he has authored about 26 papers discussing the use of low-valent titanium carbonyl coupling reactions. His review article entitled, "Carbonyl-Coupling Reactions Using Low-Valent Titanium" was published in *Chemistry Review*, Vol. 89, No. 7 in 1989. (SX 2011, ¶ 2).

32. Dr. McMurry states that the coupling of two carbonyl compounds in the presence of low-valent titanium is what characterizes a McMurry reaction. The low-valent titanium used in the McMurry Reaction can be generated using a number of reducing agents, including zinc, lithium, zinc-copper, magnesium, potassium, etc. (SX 2011, ¶ 11).

33. According to Dr. McMurry, the two parties' claims make the same compound by reacting to two similar starting ketones via the same reaction mechanism. (SX 2011, ¶ 12).

34. Dr. McMurry testifies that the only difference between Jackson '827 claim 17 and Stampa claim 2 is that Stampa's reaction takes place in the presence of a tertiary amine. (SX 2011, ¶ 12).

35. Dr. McMurry opines that the use of a tertiary amine in a McMurry Reaction is “a well-known and obvious variable” to a person of ordinary skill in the art. He further testifies that adding a tertiary amine to an identical McMurry Reaction is merely a matter of routine experimentation much as varying the reaction solvent might be. (SX 2011, ¶ 12).

36. Dr. McMurry states that there is nothing surprising in Stampa’s use of a tertiary amine in preparing loratadine because the use of a tertiary amine in a McMurry reaction is well-known and has been extensively studied. (SX 2011, ¶ 13).

37. Dr. McMurry directs the Board’s attention to a 1989 article² where he wrote:

Amines are inert to low-valent titanium, and their addition has even been recommended to improve yields in coupling reactions and to maintain basicity. The amine is usually tertiary...

(SX 2011, ¶ 13).

38. Dr. McMurry’s 1989 article also stated:

Numerous attempts have been made to improve the ease and reproducibility of low-valent titanium preparation, and the reagent systems $\text{TiCl}_4/\text{Zn}/\text{pyridine}$ and $\text{TiCl}_3/\text{K}/\text{graphite}$ have been suggested.

McMurry, *Chem Rev.*, Vol. 89, No. 7, 1513-1524, 1514 (1989) (JX 1004). (SX 2011, ¶ 13).

²McMurry, Carbonyl-Coupling Reactions Using Low-Valent Titanium, *Chem Rev.*, Vol. 89, No. 7, 1513-1524, 1516 (1989) (JX 1004).

39. Dr. McMurry testifies that there are numerous articles describing the use of tertiary amines in a McMurry reaction including: (1) Ishida et al., Chem. Lett, No. 10, 1127-1130 (1976) (SX 2014); (2) Lenoir, D., Synthesis, 553-554 (1977) (SX 2015); (3) McMurry et al., J. Am. Chem. Soc., Vol. 105, 1660-1660 (1983) (SX 2016); and (4) Camps et al., Synth. Commun., Vol 25(9), 1287-1293 (1995) (SX 2017). (SX 2011, ¶ 13).

40. Dr. McMurry testifies that the chemical literature recommends the use of tertiary amines in conducting low-valent titanium carbonyl coupling reactions, and the use of tertiary amines in a McMurry reaction would be well-known to those of ordinary skill in the art. (SX 2011, ¶ 14).

41. Dr. McMurry testifies that there is no empirical evidence to prove or disprove Professor Lectka's observations³ that the use of a tertiary amine would: (i) result in a lower chemical yield; and, (ii) cause a longer reaction time. (SX 2011, ¶ 25).

42. According to Dr. McMurry, an organic chemist may not find the differences pointed out by Professor Leckta to be material when conducting the McMurry reaction because one of ordinary skill in the art understands that they can use the McMurry reaction to make loratadine, with or without the use of tertiary amine. (SX 2011, ¶ 27).

³Dr. Lectka's testimony is discussed below in the findings of fact ¶¶ 45-50.

43. According to Dr. McMurry, removal and purification steps, e.g., removal of toxic reactants or byproducts, are a routine part of any organic work-up. (SX 2011, ¶ 30).

44. Dr. McMurry further testifies that one a person skilled in the art with the knowledge of Jackson's process would consider the addition of tertiary amine to be an obvious variable in conducting the process to prepare loratadine or other cycloheptenes. (SX 2011, ¶ 30).

B. Jackson's Expert Witness, Professor Thomas Lectka

45. Professor Thomas Lectka received his Ph.D. from Cornell University. His expertise in the area of low-valent carbonyl titanium induced coupling reactions was established as a graduate student in the labs of Professor John McMurry at Cornell University. (Declaration of Professor Thomas Lectka, JX 1007, ¶ 1).

46. Stampa does not question Professor Lectka's ability to testify as an expert witness on the involved subject matter. For example, Stampa's expert witness, Dr. McMurry stated in his declaration that "Professor Lectka was one of my graduate students and worked in my research group at Cornell...I hold Professor Lectka in the highest regard and consider him to be one of the best student[s] I have seen in more than 30 years of teaching..." (SX 2011, ¶ 24).

47. Professor Lectka testified that:

[T]he patents of Rolabo [Jackson] and Medichem [Stampa] differ from each other in a significant way: the Rolabo patented process does not require the use of a tertiary amine, such as pyridine, in the reaction mixture, while the Medichem patented process does require the use of a tertiary amine. The required use of the tertiary amine in Medichem's patented process makes that process significantly different than the process claimed in Rolabo's patent, in terms of (1) the chemoselectivity of the reaction, which directly relates to the overall yield of the process, (2) the additional steps required to remove the tertiary amine from the Medichem process after it has been used in the reaction, and (3) the reactivity of the titanium metal.

(JX 1007, ¶ 2).

48. According to Professor Lectka, "apparently small changes in reagent composition will have a large impact on the selectivity and yields of carbonyl coupling reaction," such as that claimed by Jackson and Stampa. (JX 1007, ¶ 9).

49. Professor Lectka testifies that a comparison of Jackson and Stampa's specification examples and commercial processes demonstrates that a tertiary amine free process produces higher yields of loratadine. (JX 1007, ¶ 13).

50. Professor Lectka also testifies that the use of pyridine, a tertiary amine mentioned in Stampa's specification, is toxic and will necessitate a tedious workup procedure to remove it from Stampa's resulting loratadine product. (JX 1007, ¶ 14).

9. Stampa Motion to Strike or Suppress

51. The Standing Order, Paper No. 2, provides the following mechanism for objecting to an opponent's evidentiary submission:

§ 33. Time for objection to admissibility of evidence

Any objection to the admissibility of evidence, including evidence filed with any Rule 633 preliminary motion, opposition or reply, shall be served (but not need not be filed) within **five (5) business days** of service of the evidence to which the objection is made.

§ 34. Time for serving supplemental evidence

Any supplemental evidence responding to any objection to the admissibility of evidence shall be served (but not filed) within **two (2) weeks** of the date an objection was served.

52. Jackson served Stampa Jackson exhibits JX 1001 and 1003 on April 4, 2003. (Jackson Opposition 4, Paper No. 53, fact ¶49, Stampa Reply 4, Paper No. 60, p. 2 admitting Jackson fact ¶49).

53. Stampa failed to serve objections to Jackson exhibits JX 1001 and 1003 within five (5) business days of their receipt. (Jackson Opposition 4, Paper No. 53, fact ¶¶ 51-52, Stampa Reply 4, Paper No. 60, p. 2 admitting Jackson fact ¶51-52).

IV. Opinion

There are five pending preliminary motions. Stampa has filed four preliminary motions and Jackson has filed two, with one having previously been decided.⁴ Generally, Stampa has alleged that certain Jackson claims are unpatentable for lack of definiteness, enablement and written description whereas Jackson has alleged that there is no interference-in-fact between the parties. Additionally, Stampa has requested that the Board strike or suppress two Jackson exhibits. These motions and our findings are discussed in detail below.

A. Stampa's Motion to Strike or Suppress

Stampa moves to strike or suppress Jackson exhibits JX 1001 and 1003 based upon Jackson's alleged failures to comply with the Federal Rules of Evidence ("FRE"), the Code of Federal Regulations ("CFR") and the Standing Order. (Paper No. 50, p. 9). Jackson exhibit 1001 is a four volume set of documents that contains excerpts from the Joint Appendix from the related §291 Federal Circuit appeal. (Paper No. 50, fact ¶1, Paper No. 53, admitting Stampa fact ¶1). Jackson exhibit 1003 is a declaration of a Dr. Thomas Lectka that was previously prepared and submitted in the related District Court action. (Paper No. 50, fact ¶2, Paper No. 53, admitting Stampa fact ¶2).

⁴Order, Paper No. 32 (denying Jackson's Preliminary Motion 2 for unpatentability of Stampa's reissue claims under 35 U.S.C. §135(b)(1)).

1. Stampa Failed to Timely File Their Objections to Jackson's Evidence

Interferences are time-consuming and resource intensive, both for the parties and the Board. To reduce the burden upon all involved, the Board has adopted a procedure by which a party may object to evidence and in return, an opposing party may provide supplemental evidence seeking to cure the alleged defect(s). The procedure is set forth in the Standing Order which states that "any" objection to the admissibility of evidence shall be served within five (5) business days of the service of the objectionable evidence. (Paper No. 2, ¶ 33). A party whose evidence is objected to may file responsive supplemental evidence to cure the alleged deficiencies. (Paper No. 2, ¶ 33). Among other things, by allowing a party to cure the alleged defects, the Board reduces the number of evidentiary questions that must be ultimately ruled upon.

Stampa did not provide a timely objection to Jackson exhibits 1001 and 1003. Nor did Stampa's motion to strike or suppress explain why the specific objections could not have been raised earlier. Stampa's current objection to the exhibits is not timely within the meaning of Section 33 of the Standing Order.

A violation of the Standing Order does not require automatic sanction. Yet, a failure to comply with ¶ 33 of the Standing Order normally waives a party's right to object to an opponent's evidence and precludes the filing of a motion to strike or suppress. We see no reason to hold otherwise. Stampa failed to demonstrate that the objections to Jackson's evidence could not have been timely made. Further, Stampa failed to sufficiently explain why the alleged defects are of such a character as to render Jackson's evidence of little value in this interference,

i.e., lack of authenticity, credibility, relevance, etc. Based upon the particulars of this interference, the panel concludes that Stampa's failure to timely object to Jackson exhibits 1001 and 1003 violates the Standing Order such that Stampa has waived its right to object to their admissibility. Stampa's Motion to Strike or Suppress is *denied*.

While we hold that Stampa has waived their right to object to the alleged defects in Jackson exhibits 1001 and 1003, the Board reviews the belated filing of the supplemental Dr. Lectka declaration JX 1007 nonetheless.

a. Dr. Lectka's Declaration 1007

Stampa alleges that Dr. Lectka's prior testimony exhibit 1003 must be captioned.⁵ In response to this objection, Jackson submitted a declaration by Dr. Lectka with the appropriate caption as exhibit JX 1007. (Jackson Opposition, Paper No. 53, p. 5, ¶ 54, admitted by Stampa, Paper No. 60, p. 2).

Stampa's motion to strike alleges that Dr. Lectka's original declaration, JX 1003, while containing the statement "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct" did not demonstrate that Dr. Lectka had been

⁵The Standing Order requires that the first page of all papers filed in the interference be captioned and pink. (Paper No. 2, ¶ 4). This requirement ensures the proper matching of interference papers with the appropriate interference and for the quick identification of the beginning of each individual filing.

There is no requirement that each and every piece of evidence in an interference be captioned. In filing the record, a party may file a paper identifying and listing the exhibits being submitted. Rather than captioning each individual exhibit, a party may place the appropriate caption on the list.

warned pursuant to 37 C.F.R. § 1.68 that “willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. § 1001), and may jeopardize the validity of the application or any patent issuing thereon in the instant Interference.” (Paper No. 50, p. 16). While Stampa failed to explain why the specific differences in language detracts from Dr. Lectka’s veracity, Jackson responded to this critique by filing exhibit JX 1007 with the appropriate acknowledgment that willful statements and the like are punishable and may jeopardize the interference.

The panel finds that Jackson had the ability to cure the alleged defects in Dr. Lectka’s declaration (JX1003). See, e.g., 35 U.S.C. §26. Indeed, even Stampa acknowledges that:

The belatedly-filed Jackson supplemental Exhibit 1007 appears to be the declaration of Dr. Lectka for the purposes of this Interference and appears to be in compliance with the Rules and the Standing Order.

(Paper No. 60, p. 4).

The panel concludes that Stampa’s failure to timely object to JX 1003 prejudiced Jackson’s ability to timely cure the alleged defects. Jackson’s belated supplementation of Dr. Lectka’s declaration is a direct consequence of Stampa’s failure to timely object. We therefore authorize the belated filing of Dr. Lectka’s supplemental declaration (JX 1007) and enter it into the record as a replacement for Dr. Lectka’s District Court declaration JX 1003.

b. Observations Regarding Jackson Exhibit JX 1001

We have held that Stampa has waived their objections to JX 1001 and JX 1003. This waiver does not preclude the Board from reviewing the underlying exhibits and assigning such weight, if any, to those exhibits as may be appropriate.

i. Jackson is Required to Specifically Cite and Explain Relevant Passages Contained within Voluminous Submission

Jackson exhibit JX 1001 is a voluminous, four volume, bound set of documents that contains excerpts from the related §291 Federal Circuit appeal. Given the sheer size of exhibit JX 1001, the Board has not independently reviewed Jackson's briefs to determine whether or not Jackson complied with Section §26 of the Standing Order which provides that:

Citation to the evidence must be specific, i.e., (1) by column and line of a patent, (2) page, column and paragraph of a journal article and (3) page and line of a cross-examination deposition transcript. Citations to an entire document or numerous pages of a cross-examination deposition transcript do not comply with the requirement for a citation to the record. In this respect, the Trial Section adopts as its policy the rationale of Clintec Nutrition Co. v. Baxa Corp., 44 USPQ2d 1719, 1723 n.16 (N.D. Ill. 1997), which notes that where a party points the court to multi-page exhibits without citing a specific portion or page, the court will not pour over the documents to extract the relevant information, citing United States v. Dunkel, 927 F.2d 955, 956 (7th Cir. 1991). Nor will the board take on the role of an advocate for one of the parties. Compare Ernst Haas Studio, Inc. v. Palm Press, Inc., 164 F.3d 110, 111-12, 49 USPQ2d 1377, 1378-79 (2d Cir. 1999).

Thus, while the Board is not precluded from relying upon any particular document or passage contained within the four volume set, the Board is under no obligation to sift through the volumes for those uncited and/or unexplained portions that may advance or refute a particular

position.

ii. No *Per Se* Exclusion of Testimony from Related Proceedings

The panel notes that among Stampa's various objections to JX 1001, Stampa argued that JX 1001 is not in affidavit or declaration form and that Section 1.671 of the CFR "does not allow for evidence to consist of testimony or referenced exhibits from another interference, proceeding or action." (Paper No. 50, p. 6, alleged fact ¶ 22). Stampa misconstrues the meaning of the rules.

Rule 671 specifically defines evidence as consisting of "affidavits, transcripts of depositions, documents and things." 37 C.F.R. §1.671(a). There can be no dispute that exhibit JX 1001, which includes excerpts of trial testimony from the related District Court proceeding, constitutes a document or thing. Further, as promulgated, the 1984 interference rules, from which the current rules stem, specifically contemplated the introduction of testimony from related proceedings. Indeed, the comments to the rules explicitly provide that: "[t]estimony obtained in other proceedings, e.g., another interference or an infringement action, may be used if otherwise admissible." As Rule 671 permits evidence to be in the form of documents and things and as the comments to the rules inform us that testimony obtained in other proceedings may be admitted, we find that Jackson's excerpts contained in JX 1001 are not *per se* inadmissible.

Additionally, to the extent that the excerpts are noncumulative to the present record and contain expert testimony that is inconsistent with or refutes a position advanced by either party, the parties may have been obligated to submit the excerpts pursuant to their duty of candor to the

tribunal. See, 37 C.F.R. §1.56.

2. Stampa Requests a Stipulation that Parties be Bound to Priority Dates
Determined by District Court

Stampa's motion to strike or suppress requests that the parties enter into a joint stipulation (Stampa Exhibit SX 2018) that evidence from the District Court action be used as evidence in the interference and further agree to be bound by the invention dates determined by the District Court, i.e., May 7, 1996 for Stampa and October 7, 1996 for Jackson. (Paper No. 50, p. 3). According to Stampa, entry of such a stipulation will obviate the need for a priority phase in this interference. Stampa invites the Board and Jackson's counsel to discuss this proposed judicial economy.

Stampa's request borders on frivolous. A similar request to enter the District Court's findings on priority was explicitly denied at the outset of this interference. (Notice Declaring Interference, Paper No. 1, p. 13). As previously discussed:

Stampa argues that the district court's non-appealed finding of fact on the issue of priority can be employed in a Jackson-Stampa interference. Stampa requests that Jackson be placed under an order to show cause why judgment should not be entered against Jackson on the issue of priority. (Interference No. 105,002, Paper No. 24, pages 5 and 24). Stampa's request is *denied*.

A count defines the interfering subject matter between the parties. The district court, having determined that there was no interfering subject matter, did not need to articulate a count. In contrast, the APJ has determined that there exists an interference-in-fact and declared this interference based upon Count 1, a process according to claim 17 of U.S. Patent No. 6,093,827. The parties will be afforded an opportunity to file preliminary motions, including motions to redefine the interfering subject matter under 37 C.F.R. § 1.633(c).

Stampa has made little or no effort to explain why the administering APJ's decision not to enter the District Court's finding on priority dates was made in error or was arbitrary or capricious. The Board has articulated a specific count in this interference that defines the scope of priority proofs that may be submitted in this interference. Stampa failed to explain why the District Court's findings on priority were based upon the same set of priority proofs that will be submitted in this interference. Lacking any meaningful basis to determine whether the priority proofs submitted in District Court resemble those that will be submitted in this interference, the Board again denies Stampa's request to enter the District Court's findings on priority of invention.

Additionally, another basis for denying Stampa's request is that the Federal Circuit has vacated the District Court's findings on priority of invention. The Federal Circuit did recognize however, that the District Court is free to reach the same conclusion on remand. *Medichem*, slip at 12-13.

B. Jackson's Motion for No Interference-in-Fact

Jackson has moved for judgment that there is no interference-in-fact between Jackson's involved claims and Stampa's. (Jackson Preliminary Motion 1, Paper No. 20). Stampa opposes this request. (Stampa Opposition 1, Paper No. 37).

1. Statute, Rules and Case Law on Interference in Fact

Under 35 U.S.C. § 135(a), the Director of the USPTO is authorized to declare interferences between an application for patent and any pending application or any unexpired patent. The USPTO interference rules provide that:

An interference-in-fact exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.

37 C.F.R. §1.601(j). The rules define "same patentable invention" and "separate patentable invention" as:

Invention "A" is the same patentable invention as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". Invention "A" is a separate patentable invention with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and non-obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".

37 C.F.R. §1.601(n).

Under the rules as interpreted by the Director, an interference-in-fact is established when the parties are claiming the same patentable invention. To determine whether the parties are claiming the same patentable invention, the Director applies a two-way test. This two-way test involves: 1) comparing Party A's claims with Party B's claims, assuming that Party B is prior art to A; and 2) comparing Party B's claims with Party A's claims, assuming that Party A is prior art to B. Employing this analysis, there is an interference-in-fact if: 1) Party A's claims anticipate or render obvious Party B's claims; and, 2) Party B's claims anticipate or render obvious Party A's claims. This test has been upheld by the Federal Circuit as:

the Director's two-way test avoids the proliferation of unnecessary, wasteful interference proceedings concluding that both parties are entitled to patents in situations in which the claimed inventions do not define the same patentable invention, but merely overlap in scope. This is the clear application of discretion that is inherent in the authority granted pursuant to 35 U.S.C. § 135(a) of the statute.

Lilly at 1164.

While a two-way patentability test is needed to demonstrate the existence of an interference-in-fact, a failure of the two-way test in either direction, i.e., A's claims fail to anticipate or render obvious B's claims or vice-versa, may be sufficient to demonstrate that there is no interference-in-fact between the parties. This one-way distinctiveness for no interference-in-fact is a natural consequence of the two-way test for the existence of an interference-in-fact. See, *Noelle v. Lederman*, 02-1187, slip op. at p. 16 (Fed. Cir. 2004). Thus, for Jackson to succeed in their motion for no interference-in-fact, Jackson need only establish that: 1) Jackson's process of forming loratadine does not anticipate or render obvious Stampa's tertiary amine process for forming loratadine; or 2) Stampa's tertiary amine process does not anticipate or render obvious Jackson's process.

In determining whether there is an interference-in-fact, the Board compares the party's claimed inventions. As discussed in *Noelle*:

A patentee's invention is only found in a patentee's claims, unless the patentee uses sufficient means-plus-function language to invoke 35 U.S.C. § 112, paragraph (6). Thus, if the Board is to compare two inventions, the Board must only compare the parties' claims.

Id. at 18. Thus, while the Board will interpret a party's claims in light of their specification, generally the Board will not rely upon a party's specification as prior art in conducting the test for an interference-in-fact.

2. Jackson Bears Burden of Proof

A party moving for no interference-in-fact bears the burden of proof. 37 C.F.R.

§1.637(a). The burden in a case where the application and patent are “copending” is by a preponderance of the evidence. *Cf. Bruning v. Hirose*, 161 F.3d 681, 685, 48 USPQ2d 1934, 1937-38 (Fed. Cir. 1998) (the burden of proof on the issue of patentability of the claims of a patent in an interference where applications are copending is by a preponderance of the evidence). As the Jackson application and patent were and are copending with Stampa’s patent and reissue application, Jackson bears the burden of proof by a preponderance of the evidence.

To determine whether an interference-in-fact exists we must compare the parties’ claims. Stampa’s reissue claims 1-13 are present in both the reissue and in the underlying patent. For simplicity we focus upon Stampa’s reissue claim 2, which is identical in language to Stampa’s patented claim 2 and requires a process of preparing loratadine in the presence of a tertiary amine. Further, we have chosen to focus upon Jackson patent claim 17 as well as Jackson’s application claim 17, both of which depend upon their respective claim 1 and further limit their claim 1 to a process for preparing loratadine.⁶ Jackson patent claim 1 employs the “comprising” transition whereas Jackson application claim 1 employs the “consisting essentially of” transition.

⁶The panel notes that Jackson application claim 17 appears to be an improper multiple dependent claim. 37 C.F.R. §1.75. Claims 4, 5, 6, 10, 12, 13 and 14 are all preceding claims that are themselves dependent upon more than one preceding claim. For purposes of this review, the panel will focus on Jackson application claim 17’s dependency on claim 1.

The panel additionally notes that there is a question as to whether or not Jackson paid the appropriate filing fees stemming from the use of multiply dependent claims and claims in excess of twenty.

A comparison of Jackson patent claims 1 and 17 and Stampa reissue claims 1 and 2 is provided

below:

TABLE 1 JACKSON AND STAMPA CLAIM COMPARISON	
JACKSON '827	STAMPA '659
Claim 1. A process for preparing 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-enes	Claim 1. A process for the preparation of loratadine
<i>comprising</i> reacting	consisting of reacting,
	in an <i>organic solvent</i> and in the presence of a <i>tertiary amine</i> ,
a dibenzosuberone or an aza derivative thereof	8-chloro-5,6-dihydrobenzo[5,6]cyclohepta[1,2-b]pyridin-11-one, of formula VII [structure omitted]
with an aliphatic ketone	and ethyl 4-oxopiperidine-1-carboxylate of formula IV [structure omitted]
in the presence of low valent titanium	with low-valent titanium species.
wherein said low valent titanium is generated by zinc.	Claim 2. The process of claim 1, wherein the low-valent titanium species are generated by reduction of titanium tetrachloride with zinc dust.
Claim 17. A process as claimed in claim 1 for preparing Loratadine.	

There is no dispute that Stampa's formula VII 8-chloro-5,6-dihydrobenzo[5,6]cyclohepta[1,2-b]pyridin-11-one is the specific aza derivative of a dibenzosuberone necessary to make loratadine. (SX 2011, ¶ 10). Similarly, there is no dispute that Stampa's "ethyl-4-oxopiperidine-1-carboxylate" is the specific aliphatic ketone necessary to make loratadine. (SX 2011, ¶ 10). Additionally, neither party disputes that Jackson's application claims or patented claims are open

to the inclusion of an organic solvent or that one skilled in the art would believe that the addition of a solvent to Jackson's claimed process is anything other than routine organic chemistry.

In comparing the party's claims, the Board provides the broadest reasonable interpretation. For, as discussed in the Notice Declaring Interference:

In interpreting the claims and their terms, the Board applies the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise may be afforded by written description contained in applicant's specification. *In re Morris*, 127 F.3d 1048, 1053-54, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). Indeed, the Federal Circuit has commented that:

Patent application claims are given their broadest reasonable interpretation during examination proceedings, for the simple reason that before a patent is granted the claims are readily amended as part of the examination process. [Citation Omitted]. Claims may be amended for the purpose of distinguishing cited references, or in response to objections raised under section 112. Issues of judicial claim construction such as arise after patent issuance, for example during infringement litigation, have no place in prosecution of pending claims before the PTO, when any ambiguity or excessive breadth may be corrected by merely changing the claim. *Burlington Indus., Inc. v. Quigg*, 822 F.2d 1581, 1583, 3 USPQ2d 1436, 1438 (Fed. Cir. 1987).

(Paper No. 1, pages 9-10). Additionally, there is a heavy presumption in favor of the ordinary meaning of claim language. Although the written description may aid in the proper construction of a claim term, limitations, examples or embodiments appearing only therein may not be read into the claims. *Kraft Foods Inc. v. International Trading Co.*, 203 F.3d 1362, 1366, 53 USPQ2d 1814, 1817 (Fed. Cir. 2000). Thus, while a claim must be read in light of the specification, we will rarely import an unrecited, negative limitation into a claim. *Omega Engineering Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323, 67 USPQ2d 1321, 1327 (Fed. Cir. 2003);

Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1325, 65 USPQ2d 1385, 1392-93

(Fed. Cir. 2003) (“Because the claims are best understood in light of the specification of which they are a part, however, courts must take extreme care when ascertaining the proper scope of the claims, lest they simultaneously import into the claims limitations that were unintended by the patentee.”). This is especially true for applicants as an applicant can resolve any ambiguity by amending the claim to contain the proposed limitations from the specification.

3. Stampa Claim 2 Anticipates Jackson Claim 17

a. Jackson Patent Claim 17

The principle difference between Stampa claim 2 and Jackson claim 17 is that Stampa claim 2 requires that the process of preparing loratadine occur in the presence of a tertiary amine. (Paper No. 20, p. 8, “The primary difference between the Stampa claims and the Jackson claims is that Stampa claims require the addition of a tertiary amine to its process while the Jackson claims do not.”) The Federal Circuit has determined that Jackson’s use of the term “comprising” opens the claim up to unrecited process steps. *Medichem*, slip at 9.

For anticipation the dispositive question is whether one skilled in the art would reasonably understand that all claim limitations were disclosed in a single prior art reference. *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368, 66 USPQ2d 1801, 1809 (Fed. Cir. 2003). As Jackson’s patent claim 17 allows for the presence of a tertiary amine in the claimed process of preparing loratadine, Jackson patent claim 17 is anticipated by Stampa claim 2 as Stampa claim 2 teaches all the limitations of Jackson patent claim 17. This determination is

consistent with the Federal Circuit's claim construction and interference-in-fact analysis in the related §291 proceeding.

b. Jackson Application Claim 17

To determine whether or not Jackson claim 17 is anticipated by Stampa claim 2, we must first construe Jackson claim 17. Jackson application claim 17 depends upon Jackson application claim 1, which employs the "consisting essentially of" transition. At the outset of the interference, Jackson's application "consisting essentially of" claims were tentatively construed as encompassing the use of a tertiary amine.⁷

⁷As set forth in the Notice Declaring Interference:

Jackson [application] '894 claim 1 is similar to Jackson [patent] '827 claim 1, except that Jackson '894 employs the "consisting essentially of" transitional language. The Federal Circuit has stated that:

"Consisting essentially of" is a transition phrase commonly used to signal a partially open claim in a patent. Typically, "consisting essentially of" precedes a list of ingredients in a composition claim or a series of steps in a process claim. By using the term "consisting essentially of," the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A "consisting essentially of" claim occupies a middle ground between closed claims that are written in a "consisting of" format and fully open claims that are drafted in a "comprising" format.

PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). The claimed processes of Jackson '894 claim 1 and Stampa claim 2 are directed toward the production of loratadine. The broadest reasonable construction of Jackson's use of the transitional phrase "consisting essentially of" does not exclude the presence of Stampa's tertiary amine and organic solvent.

Regarding the construction of the “consisting essentially of” transitional phrase, Jackson concludes their preliminary motion for no interference-in-fact with the following commentary:

Further, the phrase “consisting essentially of” in claims 1-17 of the Jackson continuation application excludes the use of additional reagents, such as a tertiary amine, that would have a material effect on the process. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). Since the evidence shows that the use of a tertiary amine in a McMurry reaction has a material effect, those claims do not interfere with the Stampa claims.

(Paper No. 20, p. 25).

Jackson’s brief commentary regarding the construction of the “consisting essentially of” language is surprising. Jackson’s distinction appears premised on the tertiary amines “material effect on the process.” Jackson however, fails to sufficiently explain what is meant by material effect upon the claimed process. If Jackson intends that material effect means patentable distinction, then Jackson’s statement falls short of demonstrating how their claimed process differs from Stampa’s tertiary amine process.

Jackson cites *In re Herz*, which holds that the phrase “consisting essentially of” limits the scope of a claim by excluding only those ingredients that affect the basic and novel characteristics of a composition. *In re Herz*, 537 F.2d at 551, 190 USPQ at 463. Yet, Jackson did not seek to explain what they considered to be the basic and novel characteristic of its claimed invention.

Jackson, in its reply, argues that tertiary amines are not included in Jackson’s application claims because the tertiary amine affects the basic characteristics of Jackson’s claimed method.

(Paper No. 1, pages 11-12).

(Jackson Reply 1, Paper No. 45, p. 7). Jackson's reply goes on to state that the presence of the tertiary amine "materially affects the McMurry reaction."

Jackson is not entitled to raise arguments in its reply that it could have raised earlier. (Standing Order, Paper No. 2, ¶ 31, "No new issues shall be raised in replies.") Jackson's preliminary motion could have and should have explained the basic and novel characteristic of their claimed invention. Yet, even assuming that Jackson's reply statements are not new arguments, Jackson has failed to demonstrate that the addition of a tertiary amine affects the basic and novel characteristics of its claimed invention.

Jackson application claim 17 is a process for preparing loratadine. The process involves the use of a McMurry reaction that couples two carbonyl compounds in the presence of a low-valent titanium. Jackson's specification recites "typical" reaction temperatures, times and yields as well as "non-limiting" examples. (JX 1001, col. 4, lines 2-36).⁸ Yet, Jackson application claim 17 does not recite any specific time or temperature. Further, claim 17 does not require any specific amount of the starting materials or yield or purity of the final product. We decline any invitation to read unrecited time, temperature, yield and/or purity limitations into Jackson's application claim 17 as: 1) although Jackson recited time and temperature limitations in claims 24 to 28, Jackson did not seek to add these limitations to claim 17 during the course of either *ex parte* or *inter partes* proceedings; 2) the unclaimed process characteristics are not sufficiently identified by Jackson's specification such that one skilled in the art would believe them to be so

⁸The involved Jackson '594 application is a continuation of Jackson's involved '827 patent. For simplicity, we cite to Jackson's issued '827 patent.

desired and/or necessary to the invention that they form the basic and novel characteristics of the invention;⁹ and 3) once we begin adding limitations from the specification into Jackson's claims, we will not know where to stop. Giving Jackson application claim 17 its broadest reasonable interpretation, the basic and novel characteristic of this claim is a process for preparing loratadine via a McMurry reaction in the presence of low-valent titanium.

Jackson's Preliminary Motion 1 and supporting declaration by Dr. Lectka identify three factors that allegedly confirm the "materiality" of the amine. These three factors are:

- 1) Use of a tertiary amine in Stampa's process provides lower yields;
- 2) Stampa's process requires longer reaction times; and
- 3) Stampa's process requires additional process steps to remove the tertiary amine from the loratadine.

(Paper No. 20, pages 11-12; JX 1001, A004665; JX 1007, ¶ 2). Yet, Jackson has failed to explain how these three factors patentably distinguish the claimed inventions, e.g., Jackson application claim 17 from Stampa claim 2. Neither Jackson application claim 17 nor Stampa claim 2 require a specific yield, duration or manner in which the loratadine is to be purified.

Stampa's reissue claim 2 process possesses the same basic and novel characteristic as Jackson's application claim 17 process. As stated by Stampa:

⁹For example, Jackson's specification teaches the invention as:

Thus, viewed from one aspect the present invention provides a process for preparing 5,6-dihydro-11H-dibenzo[a,d]cyclohept-11-enes [such as loratadine] comprising reacting a dibenzosuberone or an aza derivative thereof with an aliphatic ketone in the presence of low valent titanium, ie. Ti(O), Ti(I) or Ti(II) wherein said low valent titanium is generated by zinc.

(JX 1001 A000105-000109, col. 2, lines 18-24). As evident from this teaching, Jackson's broadly described invention does not require a particular time, temperature, yield, purity and/or manner in which the McMurry reaction product is purified.

Thus, Jackson claim 17 uses the same reaction mechanism, namely the McMurry reaction using low-valent titanium generated by zinc, to couple the same two starting compounds, to make the same product, loratadine.

(Paper No. 37, pages 18-19). As both Stampa reissue claim 2 and Jackson application claim 17 carry out McMurry reactions in the presence of a low-valent titanium to form loratadine, the presence of the tertiary amine in Stampa reissue claim 2 does not affect the process in any way that is claimed by Jackson application claim 17. As the presence of the tertiary amine does not alter the basic and novel characteristic of Jackson application claim 17 we conclude that the claim is open to the inclusion of the tertiary amine.

Stampa reissue claim 2 teaches a process having all recited limitations of Jackson application claim 17 but conducts the process in the presence of a tertiary amine. Jackson application claim 17 does not exclude the presence of a tertiary amine. Based upon the record presented, we conclude that Stampa reissue claim 2 anticipates Jackson claim 17.

4. Jackson Claim 17 Renders Obvious Stampa Claim 2

According to Jackson, there is no interference-in-fact between Jackson and Stampa as Jackson's claims do not render Stampa's tertiary amine process claims obvious. (Paper No. 20, p. 13). Stampa disagrees with Jackson's analysis and specifically admits that Stampa's claims are rendered obvious by Jackson. (Paper No. 37, p. 4, ¶ 10).

a. Case Law on Obviousness

As explained by the Federal Circuit in *In re Vaeck*:

[A] proper analysis under § 103 requires, inter alia, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.

In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

As to the prior art suggestion, Jackson acknowledges that the “scientific literature regarding McMurry reactions teaches many factors that may be changed to achieve a successful McMurry reaction, such as varying the conditions used to produce the low valent titanium, varying the solvent used in the reaction, and adding or removing tertiary amines.” (Paper No. 20, p. 14). Further, Stampa’s expert, Dr. McMurry, testifies that “the skilled artisan would have every motivation to carry out the reaction in the presence of a tertiary amine, since the literature advocates such use.” (SX 2011, p. 16, ¶ 26). Dr. McMurry’s testimony is consistent with an earlier review article that he wrote, where he stated:

Amines are inert to low-valent titanium, and their addition has even been recommended to improve yields in coupling reactions and maintain basicity. The amine is usually tertiary . . .

(SX 2012, McMurry, Chem. Rev., Vol. 89, No. 7, 1513-24, 1516 (1989)). Based upon the evidence of record, Jackson has failed to demonstrate that one skilled in the art would not have been motivated to add a tertiary amine to their claimed McMurry reaction.

b. A Reasonable Expectation of Success for Stampa Reissue Claim 2
Requires the Formation of a Useful Amount of Loratadine

The parties vigorously dispute whether there was a reasonable expectation of success when adding a tertiary amine to Jackson's process. In analyzing this question, we are reminded that a determination of obviousness "does not require absolute predictability of success. ... [A]ll that is required is a reasonable expectation of success." *In re O'Farrell*, 853 F.2d 894, 903-904, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

Jackson argues that there is no reasonable expectation of success as one skilled in the art could not predict in advance the effect of adding a tertiary amine to a particular McMurry reaction and that tertiary amines are known to have positive, negative and mixed effects upon McMurry reactions. (Paper No. 20, p. 14, also, see generally JX 1007). In opposition, Stampa cites McMurry's testimony that "adding a tertiary amine to an otherwise identical McMurry reaction is merely a matter of routine experimentation, much as varying the reaction solvent might be . . ." (Paper No. 37, p. 19 and SX 2011, ¶ 12).

To determine whether one skilled in the art possessed a reasonable expectation of success of adding a tertiary amine to Jackson claim 17 to arrive at Stampa's claimed invention we must first construe Stampa's claimed invention.

Stampa reissue claim 2 is a process for the preparation of loratadine via a McMurry reaction with a low-valent titanium species that is generated by reduction of titanium tetrachloride with zinc dust. This McMurry reaction is conducted in the presence of a tertiary amine.

Stampa reissue claim 2 does not recite any particular limitation on the resulting yield from their reaction. Nor does Stampa claim 2 explicitly recite a temperature, time, amount of starting materials to be used or purification method. Further, a review of Stampa's specification fails to demonstrate that such specific limitations are a necessary part of Stampa's described invention. For example, Stampa's specification states:

A preferred but not limitative sequence of operations to carry out the process of the present invention can be as follows:

- a) the low-valent titanium species are prepared by reduction of titanium tetrachloride with zinc dust in an appropriate solvent.
- b) a tertiary amine is added.
- c) a mixture of ketones VII and IV is added, and the mixture is heated for the required time to complete the reaction, and
- d) loratadine is isolated from the mixture.

(JX 1001, col. 4, lines 9-20). As Stampa's specification describes the "preferred" invention without reference to particular temperature, time, yield, purity, amounts of materials or purification methods, we will not read such limitations into Stampa reissue claim 2. Providing Stampa reissue claim 2 with its broadest reasonable interpretation we conclude that the expectation of success for reissue claim 2 is measured by the ability of one skilled in the art to conduct the described McMurry reaction in the presence of a tertiary amine such that a useful amount of loratadine is formed.¹⁰

¹⁰This reading of the claim is consistent with Stampa's conduct during the course of this interference. Specifically, Stampa filed the reissue application for the purpose of provoking this interference. In filing the reissue application Stampa filed a preliminary amendment to their claims. Stampa's preliminary amendment did not add any further limitations to Stampa reissue claim 2. (JX 1002).

- c. One Skilled in the Art Possessed a Reasonable Expectation of Success of Conducting Jackson's Claimed McMurry Process in the Presence of a Tertiary Amine to Form a Useful Amount of Loratadine

Jackson argues that the addition of a tertiary amine to a McMurry reaction can have a positive effect, a negative effect or a mixed effect. Jackson cites to trial testimony as evidence that one skilled in the art could not predict in advance what effect the addition of a tertiary amine would have on a McMurry reaction. (JX 1001, A004696-97).

Jackson admits that positive effects include the increased chemical yield of a desired end product. (Paper No. 20, p. 15, citing articles by Lenoir, JX 1001, A003126-27¹¹ and Ishida, Mukiyama, JX 1001, A003408-11¹²). As to negative effects, Jackson relies upon Dr. Lectka's testimony (JX 1007). Dr. Lectka's testimony directs our attention to a publication by Banerji et al.¹³ in 1996 (JX 1001, A003400-3405) that allegedly teaches that a systematic increase in the amount of pyridine in an McMurry reaction led to a decrease in the yield of the desired alkene

¹¹As the referenced article appears to be written in German, the panel was unable to confirm the teachings of Lenoir.

¹²The abstract of this article states:

Various carbonyl compounds undergo the reductive dimerization to produce symmetrical olefins in high yields on treatment with low valent titanium compounds, formed in situ from TiCl_4 and LiAlH_4 in the presence of a tertiary amine such as 1,8-bis(dimethylamino)-naphthalene or tri-n-butylamine.

(JX 1001, A003408).

¹³The named authors of the "Banerji et al" article are N. Balu, K. Nayak and A. Banerji. In referring to a publication, the Board normally refers to the first named author. Yet, as Dr. Lectka's testimony cites refers to the publication as "Banerji et al.," we will likewise refer to the publication as the Banerji publication.

product and an increase in the diol product. According to Jackson, "the addition of pyridine had negative effects if one sought an alkene product." (Paper No. 20, p. 16). From this Jackson concludes that one skilled in the art would not have a reasonable expectation of success of producing loratadine via a McMurry reaction in the presence of a tertiary amine.

Jackson has relied upon the Banerji article to demonstrate the potential negative effects of adding an amine to the claimed McMurry reaction. As noted by Dr. Lectka, the Banerji article indicates that: 1) the absence of pyridine yielded 50% alkene and 10% diol; 2) the addition of 1 equivalent of pyridine yielded 23% alkene and 35% diol; and 3) the addition of a ten-fold excess of pyridine yielded only trace amounts of the alkene and 73% of the diol. (JX 1007, ¶ 11 and Banerji et al., JX 1001, A003400-3405, in particular Table 1, p. 3401). Stampa's expert, Dr. McMurry testified that the addition of a tertiary amine to Jackson's claimed McMurry reaction "is merely a matter of routine experimentation as much as varying the reaction solvent might be . . ." (SX 2011, p. 8, ¶ 12). Based upon the evidence of record, we conclude that one skilled in the art would have sought to add the amine in reasonable amounts, e.g., 1 molar equivalent, given Dr. McMurry's testimony that one skilled in the art would have understood that the addition of a tertiary amine was a matter of routine experimentation and in view of Banerji's teaching that the addition of ten-fold excess may prevent the formation of a desired product. Further, we conclude that the prior art teaches away from the use of excessive amounts of a tertiary amine in a McMurry reaction, e.g., a ten-fold excess. (Banerji et al., JX 1001)).

Jackson has failed to provide sufficient credible evidence to demonstrate that one skilled in the art would not have expected the formation of loratadine when using a reasonable amount

of tertiary amine in Jackson's claimed McMurry reaction. At best, Jackson's cited testimony, including that of Dr. Lectka, Dr. Finney and Dr. Onrubia, taken in light of the prior art of record, demonstrates that the addition of the tertiary amine could result in a lower yield of loratadine. Yet, for purposes of Stampa's claims, the formation of a useful amount of loratadine is all that is required.

Jackson has cited various alleged differences between Stampa and Jackson's exemplified and commercial processes. For example, Jackson cites Dr. Lectka's testimony that Stampa's exemplified and commercial process provide lower yields due to the presence of the tertiary amine in the McMurry reaction. (Paper No. 20, p. 12, JX 1007, ¶ 13). Jackson also alleges differences in time, temperature and purification procedures. Even assuming that Jackson is correct and that there are differences in the exemplified and commercial processes between the parties, Jackson fails to demonstrate that these potential differences are relevant to a comparison of Jackson and Stampa's claimed processes. For as discussed above, neither Stampa reissue claim 2 nor Jackson patent or application claim 17 require specific times, temperatures, yields or purification steps.

Based upon the evidence of record, we conclude that there is sufficient credible evidence that one skilled in the art would have been motivated to add a reasonable amount of a tertiary amine to the McMurry process of Jackson claim 17 to maintain basicity and potentially improve yields. (See, e.g., SX 2011, ¶ 8; SX 2012, p. 1516). Further, we conclude that there is sufficient credible evidence to demonstrate that one skilled in the art would have a reasonable expectation

that the addition of a reasonable amount of a tertiary amine, such as pyridine, to Jackson claim 17 would have allowed for the production of a useful amount of loratadine.

In comparing the testimony of Dr. McMurry and Dr. Lectka, the panel concludes that both experts truly believe that their stated positions are correct. Nevertheless, to the extent the testimony conflicts, because Dr. Lectka's testimony relates more to a comparison of the parties' specifications, for the issue of an interference-in-fact, we credit the testimony of Dr. McMurry over that of Dr. Lectka. The fact that we credit Dr. McMurry does not imply that Dr. Lectka's testimony was anything other than totally honest.

Jackson had the burden of proof to establish that there was no interference-in-fact between Stampa and Jackson's claimed inventions. Jackson has failed to demonstrate that Jackson's patent and application claims are patentably distinct from Stampa's patent and reissue application claims or vice-versa. Jackson Preliminary Motion 1 is *denied*.

C. Stampa Preliminary Motions 1, 2 and 3

Stampa requests that all of Jackson's claims ('827 patent claims 1-17 and '894 application 1-28) be held unpatentable as the claims are of such breadth that they:

- 1) lack clarity under 35 U.S.C. §112, second paragraph (Stampa Preliminary Motion 1, Paper No. 26, p. 1);
- 2) lack an enabling disclosure (Stampa Preliminary Motion 2, Paper No. 27, p.1); and
- 3) lack sufficient written description (Stampa Preliminary Motion 3, Paper No. 28, p. 1).

Stampa's request is in itself overly broad. Stampa's preliminary motions fail to address each of the claims for which they request a judgment of unpatentability. For example, Stampa

Preliminary Motions 1, 2 and 3 identify claims 1, 2, 6 and 12 of the '827 patent and claims 1, 2, 6, 12, 18, 21, 23, 24 and 26 of the '894 application as being of such breadth that they are indefinite and lack sufficient written description to convey that the invention was possessed by Jackson or that one could make and use the "universe" of claimed processes.

We note that Stampa fails to specifically identify the particular basis or sufficient evidence that would support a finding that Jackson patent claims 3-5, 7-11 and 13-17, and application claims 3-5, 7-11, 13-17, 19-20, 22, 25 and 27-28 are overly broad with respect to Jackson's specification. (Jackson Opposition 1, Paper No. 41, p. 5; Jackson Opposition 2, Paper No. 42, pages 5-6; Jackson Opposition 3, Paper No. 43, p. 6). Hence, as to Jackson patent claims 3-5, 7-11 and 13-17, and application claims 3-5, 7-11, 13-17, 19-20, 22, 25 and 27-28, Stampa Preliminary Motions 1, 2 and 3 are denied.

Stampa generally alleges that Jackson's application claims lack sufficient written description for excluding a tertiary amine and are thus contrary to what Jackson regarded as their invention. (See, e.g. Paper No. 26, p. 15). As Jackson's "consisting essentially of" does not exclude tertiary amines from the claimed McMurry process, this argument is moot.

As the moving party, Stampa bears the burden of proving that they are entitled to the relief requested by a preponderance of the evidence. 37 C.F.R. §1.637(a). Stampa's general request that all of Jackson's involved claims be held unpatentable fails to sufficiently identify credible and persuasive evidence of record supporting the breadth of their request. Stampa Preliminary Motions 1, 2 and 3 are *denied* to the extent that they request that Jackson patent

claims 3-5, 7-11 and 13-17, and application claims 3-5, 7-11, 13-17, 19-20, 22, 25 and 27-28 be found unpatentable under 35 U.S.C. § 112, 1st and 2nd paragraph.

1. A Decision on Stampa's Specific Unpatentability Allegations Under 35 U.S.C. § 112 is Deferred

Under the USPTO interference rules (37 C.F.R. §1.640(b)):

Unless an administrative patent judge or the Board is of the opinion that an earlier decision on a preliminary motion would materially advance the resolution of the interference, decision on a preliminary motion shall be deferred to final hearing.

Count 1 of this interference is Jackson patent claim 17, which is directed to a process for the preparation of loratadine. Stampa's motions alleging unpatentability under 35 U.S.C. 112, 1st and 2nd paragraphs fail to explain why claim 17 is unpatentable, especially in light of Jackson example 3, which specifically describes a process of preparing loratadine via the claimed McMurry reaction. (JX 1001, A000108; Jackson '827, Example 3, col. 5, lines 11-33). As such, the panel denied Stampa Preliminary Motions 1, 2 and 3 with respect to Jackson patent claim 17.

A decision to continue the interference and reach a determination on priority of invention is not predicated upon a determination of patentability for those Jackson claims for which Stampa has articulated a specific allegation of unpatentability ('827 patent claims 1, 2, 6 and 12 and '894 application claims 1, 2, 6, 12, 18, 21, 23, 24 and 26). Specifically, as Stampa has not demonstrated that Jackson claim 17, which is the count in interference, is indefinite or otherwise unpatentable, a decision on Stampa Preliminary Motions 1 to 3 will not affect the scope of the count. Further, even if the specifically identified claims of Jackson are determined to be

unpatentable to Jackson under 35 U.S.C. §112, there remains an interference-in-fact between Stampa claim 2 and Jackson claim 17. As Jackson claim 17 impedes the grant of a patent to Stampa, there is sufficient basis to continue the interference and determine the question of priority of invention regardless of the patentability of the specifically identified Jackson claims.

An award of priority of invention against Jackson would moot the issues raised in Stampa Preliminary Motions 1 to 3. Further, Stampa has repeatedly reminded the Board of the District Court's non-binding,¹⁴ and now vacated, ruling on priority of invention against Jackson and in favor of Stampa. As a decision on Stampa's Preliminary Motions 1 to 3 is not a predicate to determining priority of invention, and as a decision on priority may moot the issues raised therein, the interference will proceed more efficiently by deferring resolution to final hearing the specifically identified unpatentability allegations in Stampa Preliminary Motions 1 to 3. Stampa Preliminary Motions 1 to 3 are:

- 1) ***Denied*** with respect to Jackson '827 patent claims 3-5, 7-11 and 13-17, and '894 application claims 3-5, 7-11, 13-17, 19-20, 22, 25 and 27-28.
- 2) ***Deferred*** with respect to Jackson '827 patent claims 1, 2, 6 and 12 and '894 application claims 1, 2, 6, 12, 18, 21, 23, 24 and 26.

D. Stampa Preliminary Motion 4

Stampa Preliminary Motion 4 requests that Jackson not be accorded priority benefit of Jackson's earlier filed PCT/GB98/00605, filed February 26, 1998, and UK Application 9703992, filed February 26, 1997. (Paper No. 29, p. 1). Jackson opposes this request. (Paper No. 44).

¹⁴See discussion above with regards to differences between District Court proceeding and USPTO proceeding, e.g., Count 1 defines priority proofs in the USPTO proceeding.

According to Stampa, Jackson's involved claims are invalid under 35 U.S.C. §112, first and second paragraph as Jackson's foreign priority applications "suffer from the same 35 U.S.C. §112 deficiencies as Jackson's '827 patent and '894 application . . ." (Paper No. 29, p. 6).

Stampa argues that for an application to be accorded the benefit of priority to a foreign application, the foreign application is required to meet 35 U.S.C. §112, first paragraph. (Paper No. 29, p. 6). As basis for this argument, Stampa cites case law regarding the requirements for 35 U.S.C. §119 priority.

Stampa has confused benefit for the claimed invention under 35 U.S.C. §119 and §120 with priority of invention benefit under 35 U.S.C. §102(g). *Cromlish v. D.Y.*, 57 USPQ2d 1318, 1319 (BPAI 2000); *Hillman v. Shyamala*, 55 USPQ2d 1220, 1221-1222 (BPAI 2000). In order to be accorded priority benefit, a priority application need only describe an enabling embodiment within the scope of the Count. *Weil v. Fritz*, 572 F.2d 856, 865-66 n. 16, 196 USPQ 600, 608 n.16 (CCPA 1978); *Hunt v. Teppschuh*, 523 F.2d 1386, 389, 187 USPQ 426, 429 (CCPA 1975).

Stampa has failed to sufficiently identify credible and persuasive evidence that Jackson's earlier filed applications do not describe and enable a process of making loratadine via the McMurry process of Count 1, i.e., Jackson patent claim 17. As the moving party, Stampa bears the burden of proving that it is entitled to the relief request. On this record, Stampa has not met their burden. Stampa Preliminary Motion 4 is *denied*.

V. ORDER

Based upon the evidence of record, it is:

Ordered that Jackson Preliminary Motion 1 requesting judgment that there is no interference-in-fact is *denied*.


Further Ordered Stampa Preliminary Motion 1 requesting judgment that Jackson's claims be found unpatentable for lack of definiteness is *deferred-in-part* with respect to Jackson '827 patent claims 1, 2, 6 and 12 and '894 application claims 1, 2, 6, 12, 18, 21, 23, 24 and 26 and *denied-in-part* with respect to Jackson '827 patent claims 3-5, 7-11 and 13-17, and '894 application claims 3-5, 7-11, 13-17, 19-20, 22, 25 and 27-28.

Further Ordered Stampa Preliminary Motion 2 requesting judgment that Jackson's claims be found unpatentable for lack of enablement is *deferred-in-part* with respect to Jackson '827 patent claims 1, 2, 6 and 12 and '894 application claims 1, 2, 6, 12, 18, 21, 23, 24 and 26 and *denied-in-part* with respect to Jackson '827 patent claims 3-5, 7-11 and 13-17, and '894 application claims 3-5, 7-11, 13-17, 19-20, 22, 25 and 27-28.


Further Ordered Stampa Preliminary Motion 3 requesting judgment that Jackson's claims be found unpatentable for lack of written description is *deferred-in-part* with respect to Jackson '827 patent claims 1, 2, 6 and 12 and '894 application claims 1, 2, 6, 12, 18, 21, 23, 24 and 26 and *denied-in-part* with respect to Jackson '827 patent claims 3-5, 7-11 and 13-17, and '894 application claims 3-5, 7-11, 13-17, 19-20, 22, 25 and 27-28.

Further Ordered Stampa Preliminary Motion 4 is *denied*.

Further Ordered that Stampa's Motion to Strike or Suppress is *denied*.


CAROL A. SPIEGEL
Administrative Patent Judge


SALLY GARDNER LANE
Administrative Patent Judge


MICHAEL P. TIERNEY
Administrative Patent Judge

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